

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only

## Pancreatin Capsules 150mg/300mg Pancreate 10000 & Pancreate 25000

### Composition:

Each capsule contains:

Pancreatin (enteric coated pellets)

equivalent to Pancreatin IP

150 mg/300 mg

Excipients

q.s.

Colour: Approved colour used in empty capsule shell and pellets.

Pancreate 10000	Pancreate 25000
<b>Pancreatin Minimicropellets with declared enzyme activity:</b>	<b>Pancreatin Minimicropellets with declared enzyme activity:</b>
Lipase 10000 USP units	Lipase 25000 USP units
Protease 37500 USP units	Protease 62500 USP units
Amylase 33200 USP units	Amylase 74700 USP units

### Pharmaceutical Dosage form

Capsule

### Clinical particulars

**Therapeutic indications:** For the treatment of pancreatic exocrine insufficiency.

### Posology and method of administration

*Adults (including the elderly) and children:*

Initially one or two capsules during or immediately after each meal. Dose increases, if required, should be added slowly, with careful monitoring of response and symptomatology. The capsules can be swallowed whole, or for ease of administration they may be opened and the granules taken with acidic fluid or soft food, but without chewing. This could be apple sauce or yoghurt or any fruit juice with a pH less than 5.5, e.g. apple, orange or pineapple juice. If the granules are mixed with fluid or food, it is important that they are taken immediately and the mixture not stored, otherwise dissolution of the enteric coating may result. In order to protect the enteric coating, it is important that the granules are not crushed or chewed. Crushing and chewing of the minimicropellets or mixing with food or fluid with a pH greater than 5.5 can disrupt the protective enteric coating. This can result in early release of enzymes in the oral cavity and may lead to reduced efficacy and irritation of the mucous membranes. Care should be taken to ensure that no product is retained in the mouth. It is important to ensure adequate hydration of patients at all times whilst dosing Pancreatin Capsules 150mg/300mg.

Fibrosing colonopathy has been reported in patients with cystic fibrosis taking in excess of 10,000 units of lipase/kg/day.

**Contraindications:** Hypersensitivity to pancreatin of porcine origin or to any of the excipients.

### Special warnings and precautions for use

Strictures of the ileo-caecum and large bowel (fibrosing colonopathy) have been reported in patients with cystic fibrosis taking high doses of pancreatin preparations. As a precaution, unusual abdominal symptoms or changes in abdominal symptoms should be medically assessed to exclude the possibility of fibrosing colonopathy, especially if the patient is taking in excess of 10,000 units of lipase/kg/day.

### Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

### Pregnancy and lactation

**Pregnancy:** For pancreatic enzymes no clinical data on exposed pregnancies are available. Animal studies show no evidence for any absorption of porcine pancreatic enzymes. Therefore, no reproductive or developmental toxicity is to be expected. Caution should be exercised when prescribing to pregnant women.

**Lactation:** No effects on the suckling child are anticipated since animal studies suggest no systemic exposure of the breast-feeding woman to pancreatic enzymes. Pancreatic enzymes can be used during breast-feeding. If required during pregnancy or lactation Pancreatin Capsules should be used in doses sufficient to provide adequate nutritional status.

### Effects on ability to drive and use machines

Pancreatin Capsules has no or negligible influence on the ability to drive or use machines.

**Undesirable effects:** In clinical trials, more than 900 patients were exposed to Pancreatin Capsules. The most commonly reported adverse reactions were gastrointestinal disorders and were primarily mild or moderate in severity. Gastrointestinal disorders are mainly associated with the underlying disease. Similar or lower incidences compared to placebo were reported for abdominal pain and diarrhoea.

### Paediatric population

No specific adverse reactions were identified in the paediatric population. Frequency, type and severity of adverse reactions were similar in children with cystic fibrosis as compared to adults

### Overdose

Extremely high doses of pancreatin have been reported to be associated with hyperuricaemia and hyperuricaemia. Supportive measures including stopping enzyme therapy and ensuring adequate rehydration are recommended.

### Pharmacological properties

#### Pharmacodynamic properties

Multienzymes (amylase, lipase, protease), ATC code: A09AA02

Pancreatin 150/300mg contains porcine pancreatin formulated as enteric-coated (acid-resistant) minimicropellets within gelatin capsules.

The capsules dissolve rapidly in the stomach releasing plenty of minimicropellets, a multidose principle which is designed to achieve good mixing with the chyme, emptying from the stomach together with the chyme and after release, good distribution of enzymes within the chyme. When the minimicropellets reach the small intestine the coating rapidly disintegrates (at pH > 5.5) to release enzymes with lipolytic, amylolytic and proteolytic activity to ensure the digestion of fats, starches and proteins. The products of pancreatic digestion are then either absorbed directly or following further hydrolysis by intestinal enzymes.

Treatment with Pancreatin Capsules markedly improves the symptoms of pancreatic exocrine insufficiency including stool consistency, abdominal pain, flatulence and stool frequency, independent of the underlying disease.

### Paediatric population

In cystic fibrosis (CF) the efficacy of Pancreatin Capsules was demonstrated in 288 paediatric patients covering an age range from newborns to adolescents. In all studies, the mean end-of-treatment CFA values exceeded 80% on Pancreatin Capsules comparably in all paediatric age groups.

### Pharmacokinetic properties

Pharmacokinetic data are not available as the enzymes act locally in the gastrointestinal tract. After exerting their action, the enzymes are digested themselves in the intestine.

**Storage Instructions:** Store protected from light & moisture at a temperature not exceeding 30°C

PRESENTATION: 10x10 Capsules

Marketed by :



AN GMP & ISO 9001 : 2008 Certificate Co.

\*Accreditation of Australia, Dubai & New Zealand

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(A WHO-GMP CERTIFIED COMPANY)

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